IN THE UNITED STATES PATENT OFFICE

Applicant : Jacques THILLY et al.

Appl. No. : 10/566,615

Int. Appl. No. : PCT/EP04/08703
Int. Filing Date : 2 August 2004
Title : Novel Device

Grp./A.U. : To be assigned Examiner : To be assigned

Conf. No. : 7423

Docket: : VB60431USw

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371

The following is in response to the Notification of Missing Requirements dated May 23, 2006. Applicants hereby request a 2-month extension of time to extend the response period up to and including September 23, 2006. The Commissioner is hereby authorized to charge such fees and any other fees required or credit any overpayment to Deposit Account No. 07-1392.

A Listing of the Claims in the Preliminary Amendment Filed With the **Application** appear on page 2 of this document.

Remarks appear on page 7 of this document.

LISTING OF CLAIMS IN THE PRELIMINARY AMENDMENT FILED WITH THE APPLICATION

Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

- 1. (Original) An elastomer material having an absorption coefficient for laser light of $0.5 2.5 \text{ mm}^{-1}$.
- 2. (Original) An elastomer material according to claim 1 comprising a base thermoplastic elastomer compounded with a colourant to have the absorption coefficient for laser light of $0.5 2.5 \text{ mm}^{-1}$.
- 3. (Currently Amended) An elastomer material according to elaim 1 or claim 2 wherein the base thermoplastic elastomer has a melting point of 200°C or less.
- 4. (Currently Amended) An elastomer material according to claim 2 or 3 wherein the base thermoplastic elastomer is a styrene-ethylene/butylene-styrene thermoplastic elastomer, or a styrene/butadiene/styrene tri-block copolymer or styrene-(butadiene/butylene)-styrene tri-block copolymer.
- 5. (Currently Amended) An elastomer material according to claim 2, 3 or 4 wherein the base thermoplastic elastomer is selected from the materials Evoprene™, Cawiton™, and C-Flex.
- 6. (Currently Amended) An elastomer material according to any one of claims 2 to 5 claim 2 wherein the colourant comprises a pigment or mixture of pigments mixed with a carrier material.

- 7. (Currently Amended) An elastomer material according to claim 6 wherein the pigment or mixture thereof has the colour Pantone 5497C, 556C, 5565C, 563C, 570C, <u>5</u>555C or a similar grey or grey-green colour.
- 8. (Currently Amended) An elastomer material according to 6-or claim 7 wherein the colourant comprises a mixture of the pigments (:) white 6, black 7, green 7 and blue 29.
- 9. (Currently Amended) An elastomer material according to claim 6, 7 or 8 wherein the carrier material comprises ethylene vinyl acetate, low density polyethylene or polypropylene
- 10. (Currently Amended) An elastomer material according to any of the claims 7 to 10 to claim 6 wherein the colourant comprises 10 50 wt.% pigment, the balance up to 100% comprising the carrier material.
- 11. (Currently Amended) An elastomer material according to any of the claims 7 to 11 to claim 6 comprising 1 15wt.% of colourant the balance up to 100% comprising the base thermoplastic elastomer.
- 12. (Currently Amended) An elastomer material according to claim 1 which comprises Evoprene™ Super G, compounded with 1 5 wt% of a colourant masterbatch comprising an ethylene vinyl acetate carrier with 35 45wt% of pigment of a colour Pantone 5497C, 556C, 5565C, 563C, 570C, <u>5</u>555C or a similar grey or grey-green colour.
- 13. (Currently Amended) An elastomer material according to claim 1 which comprises Evoprene™ TS2525, compounded with 1 5 wt% of a colourant master batch comprising an ethylene vinyl acetate carrier with 35 45wt% of

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pigment of a colour colour Pantone 5497C, 556C, 5565C, 563C, 570C, <u>5</u>555C or a similar grey or grey-green colour.

- 14. (Currently Amended) An elastomer material according to claim 1 which comprises Cawiton™ PR5947, compounded with 3 15 wt% of a colourant master batch comprising an LDPE carrier with 15 20 wt% of pigment of a colour Pantone 5497C, 556C, 5565C, 563C, 570C, <u>5</u>555C or a similar grey or grey-green colour.
- 15. (Currently Amended) An elastomer material according to one of the preceding claims claim 1 which in a thickness ca 2mm allows less than 6% of laser power up to 8W incident power to pass through.
- 16. (Currently Amended) An elastomer material according to one of the preceding claims claim 1 having an absorption coefficient in the range of 1.0 2.5 mm⁻¹.
- 17. (Currently Amended) An elastomer material according to <u>claim1</u>6 having an absorption coefficient <u>of 1.5 2.2 mm⁻¹</u>.
- 18. (Currently Amended) An elastomer material according to <u>claim 18</u> having an absorption coefficient <u>of</u> 1.4 1.6 mm⁻¹.
- 19. (Currently Amended) A closure for a pharmaceutical vial made wholly or partly of an elastomer material as claimed in <u>any</u> one of the preceding claims in <u>claim 1</u>.
- 20. (Original) A closure for a pharmaceutical vial having a closure wall comprised of an elastomer material such that when laser light is directed on the

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outer surface of the closure wall 99% of the laser power is absorbed within 0.5 – 2.5 mm depth from the outer surface with the effect of melting the material.

- 21. (Currently Amended) A closure for a pharmaceutical vial, made wholly or partly of a thermoplastic elastomer compounded with a colourant to the extent that less than 6% of laser light of wavelength 980nm at an incident laser power up to 8W penetrates through the closure to reach the interior of the vial or syringe.
- 23. (Currently Amended) A process for introducing a substance into a vial comprising: providing a vial having a mouth opening closed by a closure as claimed in any one of claims 19 to 21 claim 19, passing a hollow needle through the closure, introducing <u>a</u> the substance into the vial via the needle, withdrawing the needle from the vial and closure, and sealing the residual puncture hole in the closure by heat sealing.
- 24. (Currently Amended) A <u>The</u> process according to claim 23 wherein the heating heat sealing of the elastomer material of the closure adjacent the puncture site so that the material fuses is done by directing laser light onto the elastomer material adjacent the puncture site.
- 25. (Currently Amended) A <u>The</u> process according to claim 24 wherein the laser light has a power less than 20W.
- 26. (Currently Amended) A <u>The</u> process according to claim 25 wherein the laser light has a power 4 10W.
- 27. (Currently Amended) A <u>The</u> process according to any one of claims 24 to 26 claim 24 wherein the laser beam light has a wavelength in the range <u>of</u> 960-1000nm.

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28. (Currently Amended) A <u>The</u> process according to any one of claims 24 to $\frac{27}{2}$ claim 24 wherein the laser light is directed at the elastomer material adjacent to the puncture site for a period of 0.5 - 2 seconds.

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REMARKS / ARGUMENTS

Claims 1-28, as filed in the Preliminary Amendment on January 31, 2006,

are pending in this application.

The Notification of Missing Requirements dated May 23, 2006, requires an

oath or declaration of the inventors, a surcharge of \$130 for late submission of an

oath or declaration, and additional claims fees of \$460 as follows:

\$100 for 10 claims over 20

\$360 for multiple dependent claim surcharge

Applicants hereby submit a Declaration of the inventors along with a

surcharge of \$130. However, Applicants further submit that no multiple

dependent claims were present in the Preliminary Amendment filed with the

application, and there are only 8 claims over 20, which the proper fees were paid

at the time of filing the application.

In a telephone conversation with Vonda Wallace of the USPTO, claim 28

was identified as being a multiple dependent claim. In the listing of claims in the

Preliminary Amendment, claim 28 is dependent on claim 24 only.

In view of the above, Applicants request that the additional claims fees of

\$460 be removed from the requirements set forth in the Notification of Missing

Requirements.

Respectfully submitted,

Dated: August 28, 2006

/Michael M. Conger/

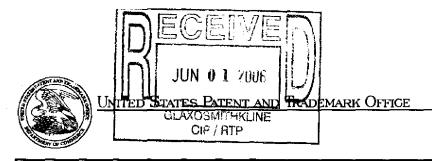
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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Tradomark Office Address COMMISSIONER FOR PATENTS

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U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

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10/566.615

Jacques Thilly

INTERNATIONAL APPLICATION NO.

PCT/EP04/08703

I.A. FILING DATE

PRIORITY DATE

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08/04/2003

20462 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939

23 July 2006

CONFIRMATION NO. 7423
371 FORMALITIES LETTER
OC000000018904906

Date Mailed: 05/23/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/31/2006
- Copy of the International Search Report filed on 01/31/2006
- Preliminary Amendments filed on 01/31/2006
- Information Disclosure Statements filed on 01/31/2006
- Request for Immediate Examination filed on 01/31/2006
- U.S. Basic National Fees filed on 01/31/2006
- Priority Documents filed on 01/31/2006
- Specification filed on 01/31/2006
- Claims filed on 01/31/2006
- Abstracts filed on 01/31/2006
- Drawings filed on 01/31/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$460 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application
 by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath

or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$590 for a Large Entity:

- \$130 Surcharge.
- Total additional claim fee(s) for this application is \$ 460
 - \$100 for 10 total claims over 20.
 - \$360 for multiple dependent claim surchare.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

VONDA M WALLACE

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PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/566,615	PCT/EP04/08703	VB60431

FORM PCT/DO/EO/905 (371 Formalities Notice)